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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
RAWLINGS, STEPHEN L	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 06/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/744,866	AUSTRUP ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2005 and 17 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,22 and 24-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,22 and 24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 January 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed January 18, 2005 is acknowledged and has been entered. Claims 10 and 23 have been canceled. Claims 1, 3, and 22 have been amended. Claims 24-27 have been added.

2. The supplemental response filed March 17, 2005 is acknowledged and has been entered.

3. The declaration under 37 C.F.R. § 132 by Prof. Dr. Michael Giesing filed March 17, 2005 is acknowledged and has been entered.

4. Claims 1-7, 22, and 24-27 are pending in the application and are currently under prosecution.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. The following Office action contains NEW GROUNDS of rejection necessitated by amendment.

Grounds of Objection and Rejection Withdrawn

7. Unless specifically reiterated below, Applicant's amendment filed January 18, 2004 has obviated, or rendered moot the grounds of objection or rejection set forth in the previous Office action mailed July 23, 2004.

Grounds of Rejection Maintained

Claim Rejections - 35 USC § 102

8. The rejection of claims 1-4, 6, 7, 22, and 25-27 under 35 U.S.C. 102(b) as being anticipated by Rye et al. (of record) is maintained.

At pages 12-14 of the amendment filed January 18, 2005, Applicant has traversed this ground of rejection.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

The claims are drawn to a method for isolating disseminated tumor cells from a cell-containing body fluid, particularly blood or bone marrow, said process consisting essentially of separating cellular components from non-cellular components of the body fluid and passing the part of the fluid containing the cells through a screen having a pore width of about 20 μm, whereby isolated disseminated tumor cells, which are retained on the screen, are provided.

The On-line Medical Dictionary (published at the Dept. of Medical Oncology, University of Newcastle upon Tyne © Copyright 1997-2004 - The CancerWEB Project), which is available on the Internet at http://cancerweb.ncl.ac.uk/omd/, defines "disseminated disease" as follows: "Disease in which the cancerous cells have spread from the tissue of origin to other organs".

As noted previously, Rye et al. teaches a method for isolating disseminated tumor cells from blood, bone marrow, ascitic or pleural fluids, and enzyme-digested tissue biopsies; see entire document (e.g., the abstract). Although Rye et al. does not explicitly refer to the isolated tumor cells as disseminated tumor cells, it is clear that the tumor cells from the blood and bone marrow of the patients had disseminated from breast cancers or malignant melanomas, as the tumor cells were isolated from anatomical site distant from the anatomical site of the primary tumor (see the definition provided above). Rye et al. teaches passing a cell-containing body fluid or part thereof through a screen having pores of a width of 20 microns (μm); see, e.g., the abstract. More particularly, Rye et al. teaches samples are prepared by subjecting peripheral blood and bone marrow specimens to Lymphoprep™ density gradient centrifugation, a process that separates the cellular components of the specimens from non-cellular components (page 100, column 2). Rye et al. teaches the fraction containing the mononuclear cells is removed

from the gradient and then the cells contained therein are washed and collected by centrifugation (page 100, column 2). The collected cells (i.e., the cell pellets) are resuspended in a suspension medium, namely Dulbecco's minimal essential medium (page 100, column 2). The suspension of cells is passed through a 20-micron nylon microfilament filter and obtaining a retained fraction of cells comprising the disseminated tumor cells (page 101, column 1).

Although Rye et al. teaches an additional step, namely incubating the suspension of cells with a primary antibody bound to magnetic beads and magnetically separating tumor cells bound by the antibody from other cells not bound by the antibody (page 101, column 1), is performed before filtration, the specification teaches that such a step can be performed before filtration at page 13, lines 25-32. Therefore, the inclusion of this additional step of which the process disclosed by the prior art is comprised is not deemed to materially affect the basic and novel characteristics of the claimed invention, as disclosed by the specification.

In addition, Rye et al. teaches the filter-isolated cells are cultured on the filters in growth medium, such that the isolated disseminated tumor cells grow, i.e., proliferate (page 101, paragraph bridging columns 1 and 2). The progeny of the filter-isolated tumor cells, which grow on the filter, are free of the separating agent used, since the separating agent does not detach from the parental cells originally retained on the filter to reattach to the progeny. Alternatively, Rye et al. teaches the filter-isolated cells are harvested from the filter, so that the cells can be processed for immunohistochemical analysis as cytospin preparations (page 101, column 2).

Thus, Rye et al. teaches a method for isolating disseminated tumor cells comprising passing a body fluid through a porous screen having pores of a diameter of 20 mm, which provides isolated disseminated tumor cells retained on the screen. Accordingly, absent a showing of any difference, the process disclosed by the prior art and the process claimed are deemed the same.

Turning to specifically address Applicant's arguments, although Applicant has argued the process disclosed by the prior art "can" provide an altered disseminated cell product (page 12, paragraph 6), apparently it is Applicant's admission that the prior process does not necessarily do so.

Nevertheless, in response to Applicant's argument that the references fail to show certain features of Applicant's invention, it is noted that the features upon which Applicant relies (i.e.,

the isolated tumor cells are essentially unaltered) are not recited in the most of the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claim 25, on the other hand, recites a limitation requiring the material of the screen to allow disseminated tumor cells to be isolated essentially unaltered. Even this claim, however, does not require the isolated disseminated tumor cells to be unaltered, as it merely required the material of which the screen is composed to be suitable for isolated such unaltered tumor cells.

Assuming *arguendo*, the claims were to be interpreted as being directed to a process that necessarily yields disseminated tumor cells that are "essentially unaltered", it is noted that the specification defines this term at page 5, lines 21-24, as meaning "not attached to constructs due to the isolation procedure, such as glass beads". As explained above, the process disclosed by the prior art does indeed yield tumor cells that are free of the separating agent used. Moreover, the progeny of the filter-isolated disseminated tumor cells are not attached to the separating agent and therefore cannot be distinguished from the disseminated tumor cells, which were originally present in the bodily fluid from which they were isolated.

Again, assuming *arguendo*, that the claims were interpreted as requiring the isolated tumor cells to be "essentially unaltered", the specification further describes such disseminated tumor cells that are isolated using the invention as "culturable ex vivo and represent[ing] in bioassays a faithful image of their original state in body fluid" (page 5, line 24). The specification additionally describes the state of the isolated disseminated tumor cells as "a state which the relevant cell may adopt in a body fluid of a human or non-human animal individual, in particular relation to physiology, morphology and /or expression profile" (page 19, lines 25-29). The specification discloses that parameters relating to the cell cycle, activation, proliferation, and apoptosis are important for describing the biological state of the isolated disseminated tumor cells (page 19, lines 30-32) and further discloses, "said parameters are left essentially unchanged by the isolating process of the invention" (page 19, liens 32-34). At page 101, in the paragraph bridging both columns, Rye et al. teaches the filter-isolated cells were cultured on the filters in growth medium, such that the isolated disseminated tumor cells grew, i.e., proliferated (page 101, paragraph bridging columns 1 and 2). Inasmuch as the of the process of the prior art

isolated tumor cells are indeed capable of proliferating, it appears the process of the prior art yields isolated tumor cells, which were originally disseminated and present in a bodily fluid, that faithfully represent in a bioassay of proliferation their original state in that bodily fluid and are therefore essentially unaltered.

Thus, for all of these reasons, despite Applicant's argument that the prior art fails to anticipate the claimed invention, absent a showing of any difference, the process of the prior art and the disclosed process that is claimed are indistinguishable.

At page 13 of the amendment, Applicant has asserted that if in some cases in the procedure of Rye et al., there is a probability that there may be no alteration in cells isolated, there still no anticipation. Applicant has remarked that anticipation may not be established by probabilities. This argument is not persuasive, as the claims do not require the isolated tumor cells to be essentially unaltered; but even so, as explained above, there is no question that the process of the prior art is capable of producing isolated tumor cells that are essentially unaltered.

At page 13, paragraph 2, Applicant has asserted that although the cells isolated by the process disclosed by the prior art are able to proliferate, the proliferative capacity of the cells does not indicate that the cells have not been altered. This argument appears inconsistent with the written description of the claimed invention. As explained above, the specification (e.g., at page 19) describes such cells as cells that retain the ability to proliferate.

Notably, the specification also teaches the biological parameters that describe the isolated tumor cells (e.g., their proliferative capacity) are left essentially unchanged by the isolating process of the invention. However, while the claims do not necessarily require the proliferative capacity of the produced isolated tumor cells to be unchanged, if, for the sake of argument, the process of the prior art changes their proliferative capacity, the burden is upon the Applicant to prove that the tumor cells necessarily produced by the process of the prior art are different than those produced by the claimed process. The Office does not have the facilities for examining and comparing the products of the process of the prior art and the products of the claimed process in order to establish that processes necessarily yield products that are distinguishable. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA, 1977) and *Ex parte Gray*, 10 USPQ2d 1922 1923 (PTO Board of Patent Appeals and Interferences, 1988 and 1989).

Applicant's remaining arguments at pages 13 and 14 are noted, but these arguments are largely reiterative of their preceding arguments and the discussion above adequately serves to address the merit of these arguments.

9. The rejection of claims 1-4, 6, 7, 22, and 25-27 under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,265,229-B1 (of record) is maintained.

At pages 14 and 15 of the amendment filed January 18, 2005, Applicant has traversed this ground of rejection.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

US Patent No. 6,265,229-B1 ('229) teaches a method for isolating micrometastatic tumor cells from various bodily fluids, including blood, bone marrow, and effusions, which comprises filtering a suspension of cells through a porous membrane having preferably 20 micron pores and obtaining a retained fraction of cells comprising the disseminated tumor cells; see entire document (e.g., column 4, lines 54-67; column 10, lines 42-47; and column 11, lines 52-60). Although '229 does not explicitly refer to the isolated tumor cells as disseminated tumor cells, it is clear that in practicing the disclosed methods, the tumor cells isolated from the blood or bone marrow of the patients diagnosed with non-hematological malignancies, i.e., breast cancer, would have to have disseminated from the anatomical site of origin, or the primary tumor (see the definition provided in the rejection above). Furthermore, '229 refers to these cells as micrometastatic (see, e.g., column 12, lines 6-14); and it is noted that similarly the specification uses the term "micrometastasized" to refer to a subgenus of disseminated cancer cells at page 7, lines 3-7). In addition, '229 teaches that the specimens of blood and bone marrow are prepared by density gradient centrifugation, providing the example of Lymphoprep™ density gradient centrifugation, followed by washing and resuspension in a resuspension medium; see, e.g., column 7, lines 19-27. Moreover, '229 teaches the fraction containing the mononuclear cells are separated and the cells contained therein are washed, collected by centrifugation, and resuspended prior to passing the resulting cell suspension through the filter; see e.g., column 7, lines 19-27.

Furthermore, '229 teaches the separated cells isolated using the filter are cultured on the filter by placing the filter directly in a culture medium, allowing the isolated cells to divide and grow (column 11, lines 52-60). The progeny of the filter-isolated tumor cells, which grow on the filter, are free of the separating agent used, since the separating agent does not detach from the parental cells originally retained on the filter to reattach to the progeny.

Additionally, although '229 teaches the disclosed invention provides isolated disseminated tumor cells, which do not need to be removed from the filter, '229 discloses that the prior art taught the removal of isolated tumor cells from a filter used in the isolation process; see, e.g., column 2, lines 36-48).

Thus, '229 teaches a method for isolating disseminated tumor cells comprising passing a body fluid through a porous screen having pores of a diameter of 20 mm, which provides isolated disseminated tumor cells retained on the screen and free of the separating agent used. Therefore, absent a showing of any difference, the process disclosed by the prior art and the process that is claimed are deemed the same or indistinguishable.

In particular, Applicant has argued that the process of the prior art is distinguishable from the claimed invention, since the process of the prior art uses an antibody and beads. This argument is sufficiently addressed in the response to Applicant's arguments traversing the rejection above.

Claim Rejections - 35 USC § 103

10. The rejection of claims 1, 3, 4, and 5 under 35 U.S.C. 103(a) as being unpatentable over Rye et al. (of record) or US Patent No. 6,265,229-B1 (of record) in view of Hirte et al. (of record) is maintained.

At pages 15-18 of the amendment filed January 18, 2005, Applicant has traversed this ground of rejection.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

Rye et al. and US Patent No. 6,265,229-B1 teach that which is set forth above in the respective rejections under 35 USC § 102.

However, neither Rye et al. nor US Patent No. 6,265,229-B1 expressly teach suggest removing the retained disseminated tumor cells from the screen, i.e., the filter "by passing a liquid through the screen in a direction opposite to that in which the body fluid or part thereof or resuspended cell-containing fraction is passed" (claim 5).

Hirte et al. teaches a method for isolating tumor cells from a body fluid or part thereof, which comprises passing the body fluid or part thereof through a porous mesh filter, such that the tumor cells are retained on the filter, and isolating the retained cells by a backwashing; see entire document, particularly the abstract and page 224, column 1.

One of ordinarily skilled in the art at the time of the invention would have understood that the process of backwashing disclosed by Hirte et al. comprises passing a liquid through the filter in a direction opposite to that in which the body fluid or part thereof containing the cells is first passed. Therefore, it would have been obvious to one ordinarily skilled in the art at the time of the invention to isolate the disseminated tumor cells retained on the filter after passing the body fluid or part thereof containing the tumor cells through the filter, such the tumor cells are retained on the filter, by backwashing, i.e., passing a liquid through the filter in a direction opposite to that in which the body fluid or part thereof containing the cells is first passed, because both Rye et al. and US Patent No. 6,265,229-B1 teach or suggest removing the tumor cells retained on the filter for further use of the isolated cells and because Hirte et al. teaches the removal of the tumor cells can be accomplished by such a process. One ordinarily skilled in the art would have been motivated to do so at the time the invention was made to isolate tumor cells free of the filter used in the isolation process so that the cells can be further analyzed by means not so adaptable to cells retained on the filter, such as immunohistochemical analysis on cytospin preparations.

In particular, Applicant has argued that the claim amendments filed January 18, 2005 specifically exclude the processes disclosed by the prior art. For the reasons provided above, contrary to Applicant's assertion, the prior art teaches processes that are not excluded from the subject matter that is encompassed by the claims.

Applicant has discussed differences between ascitic fluid and bone marrow or blood in an apparent attempt to distinguish the process disclosed by Hirte et al. from the claimed invention. In response to such arguments against any one of the references individually, one cannot show

nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Nevertheless, the differences between ascitic fluid and bone marrow or blood are not believed pertinent. While neither Rye et al. nor US Patent No. 6,265,229-B1 expressly teach removing the retained disseminated tumor cells from the screen, i.e., the filter "by passing a liquid through the screen in a direction opposite to that in which the body fluid or part thereof or resuspended cell-containing fraction is passed", as recited in claim 5, Hirte et al. teaches a method for isolating tumor cells from a body fluid or part thereof, which comprises passing the body fluid or part thereof through a porous mesh filter, such that the tumor cells are retained on the filter, and isolating the retained cells by a backwashing. Thus, the issue, here, is not whether it would have been obvious to isolated disseminated tumor cells from ascitic fluid, as opposed to bone marrow or blood, but whether it would have been obvious to practice the invention in accordance with claim 5. As explained above, it would have been obvious to isolate the disseminated tumor cells retained on the filter after passing the body fluid or part thereof containing the tumor cells through the filter, such the tumor cells are retained on the filter, by backwashing, i.e., passing a liquid through the filter in a direction opposite to that in which the body fluid or part thereof containing the cells is first passed, because both Rye et al. and US Patent No. 6,265,229-B1 teach or suggest removing the tumor cells retained on the filter for further use of the isolated cells and because Hirte et al. teaches the removal of the tumor cells can be accomplished by such a process.

At pages 16-18, Applicant addresses the merit of data, which Applicant has asserted shows that disseminated tumor cells isolated in accordance with the invention correlated with the clinical outcome of the patients, whereas cells isolated by immunomagnetic separation did not. This discussion is noted; however, it is not considered pertinent to the determination that the claimed invention would have been obvious over the cited prior art.

New Grounds of Rejection

11. Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described

in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 24 is drawn to the method of claim 1 or claim 3, wherein the disseminated tumor cells are not modified prior to screening.

Applicant has asserted that written support for the negative limitation is found in the specification at page 13, lines 25-32.

Contrary to Applicant's assertion, the specification, including the claims, as originally filed, does not appear to provide proper and sufficient written support for the negative limitation recited in claim 24. Any claim containing a negative limitation, which does not have basis in the original disclosure, should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The disclosure to which Applicant has referred at page 13 of the specification positively re recites the inclusion of a step comprising modifying the tumor cells before passing a suspension of the cells through a screen. However, the mere presence of a positive recitation is not basis for exclusion. Any negative limitation or exclusionary proviso must have basis *in the original disclosure.* The disclosure, as originally filed, does not provide the necessary support for the recitation of this negative limitation in the claims, because the disclosure does not teach the exclusion of a step in which the tumor cells are modified (e.g., by attaching the cells to particles comprising an antibody) before passing a suspension of the cells through the screen). While at page 19 the disclosure teaches the cancer cells are successfully provided as isolates from bodily fluids, which are free from the separating agent used, e.g., a particle comprising an antibody, this disclosure does not teach the exclusion of a step comprising attaching a particle comprising an antibody to the cells before passing the sample through a screen. Furthermore, while at pages 5 and 6 the specification teaches some limitations associated with the antigen-specific immunoadsorption-based methods, at page 13 the specification clearly teaches the invention can comprise modifying the cancer cells by attaching particles comprising antibodies prior to the step of screening.

Adding the expressed exclusion of certain elements implies permissible inclusion of all other elements not so expressly excluded. This clearly illustrates that such negative limitations, in fact, introduce new concepts. See *Ex parte Grasselli*, 231 USPQ 393 (BPAI 1983). Furthermore, Applicant is reminded that it cannot be said that a subgenus is necessarily

described by a genus encompassing it and a species upon which it reads. See *In re Smith*, 173 USPQ 679, 683 (CCPA 1972).

Noting that Applicant has referred to various case law, including the decision rendered by the Court in deciding *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187 (CCPA 1977), MPEP § 2173.05(i) states on the basis of such case law, including *In re Johnson:* "Any negative limitation or exclusionary proviso must have basis **in the original disclosure**" (emphasis added). In deciding *In re Johnson*, the Court indicated that since appellant had described the genus *and* the species, which appellant had deliberately excluded from the claimed subject matter by the proviso exclusion of those species, appellant had not created "an artificial genus" (or an inadequately described subgenus), because the specification, having described the whole, must necessarily have described the part remaining after the proviso exclusion of the species. In this instance, however, Applicant's original disclosure does not include a description of the species Applicant wishes to exclude. In deciding *Ex parte Grasselli*, the Board indicated that such an attempt to exclude species of a genus, which had not been described, introduces new matter into the specification as originally filed. See also *In re Welstead*, 174 USPQ 449 (CCPA 1972); and *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971). See MPEP § 2163.

12. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 recites the method according to claim 3, where the cell-containing fraction obtained constitutes mononuclear cells obtained by density gradient separation and washing and the cell-containing fraction which is resuspended constitutes the washed density gradient separated mononuclear cells. There is no antecedent basis to support this limitation, as neither claim recites the steps of obtaining mononuclear cells by density gradient separation and washing. The claim fails to particularly and distinctly claim the subject matter that is regarded as the invention, since it cannot be determined if the invention necessarily includes steps of obtaining mononuclear cells by density gradient separation and washing. Accordingly, it would not be possible to determine if a method comprising separating cellular components from non-

cellular components in a body fluid to obtain a cell-containing fraction by any other means would infringe that subject matter regarded as the invention.

Conclusion

13. No claim is allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
June 6, 2005

LARRY R. HELMS, PH.D
PRIMARY EXAMINER